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JUN - 3 2011

510 (k) Summary of Safety and Effectiveness for iPlan

Manufacturer:

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Submitter: Mr. Rainer Birkenbach

Contact Person: Mr. Alexander Schwiersch

Summary Date: April 21, 2011

Device Name:

Trade name: iPlan Cranial, iPlan Stereotaxy
iPlan ENT, iPlan Spine, iPlan View

Common/Classification Name: Planning System, Stereotactic Instrument

Predicate Device:

iPlan (K053127)

Device Classification Name: Instrument, Stereotaxic
Regulatory Class: Class II

Indications For Use:

iPlan's indications for use are the viewing, presentation and documentation of medical imaging, including different modules for image processing, image fusion, atlas assisted visualization and segmentation, intraoperative functional planning where the output can be used e.g. with stereotactic image guided surgery or other devices for further processing and visualization.

Example procedures include but are not limited to:

- Planning and simulation of cranial surgical procedures such as tumor resection, shunt placement, minimal-invasive stereotactic interventions, biopsy, trajectory planning for stimulation and electrode recording
- ENT procedures such as sinus surgery, tumor surgery
- Spine procedures such as tumor surgery, pedicle screw planning, vertebroplasty planning
- iPlan View is an application which is intended to be used for reviewing existing treatment plans

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Typical users of iPlan are medical professionals, including but not limited to surgeons and radiologists.

Device Description
Following planning sub-modules are available in the functional applications:

#	Sub-module	Changed *)	iPlan Cranial	iPlan ENT	iPlan Stereotaxy	iPlan Spine	iPlan View
1	Load and Import	yes	X	X	X	X	X
2	View and Adjustment	yes	X	X		X	X
3	Registration Points	yes	X	X	X	X	
4	ACPC Localization	yes			X		
5	Localization	yes			X		
6	Image Fusion	yes	X	X	X	X	X
7	Object Creation	yes	X	X	X	X	
8	Advanced Object Planning	yes	X	X			
9	BOLD MRI mapping	yes	X		X		
10	Fiber Tracking	yes	X		X		
11	Trajectory planning	yes	X	X		X	
12	Stereotactic planning	yes			X		
13	Electrode recording	yes			X		
14	Save and Export	yes	X	X	X	X	

*) changed compared to previous iPlan version

Description of sub-modules:

#	Sub-module	Description
1	Load and Import	Load existing treatment data from different data sources, Import patient data from DICOM or other archive types, manage (delete/copy/move) patient folders
2	View and Adjustment	Review patient data in various reconstructions or overlay, side-by-side comparison of different modalities, aligning the data set orientation, import or export screenshot images
3	Registration Points	Automatic detection of CT or MR registration markers for navigation, manual placement of markers and anatomical landmarks
4	ACPC Localization	This planning task allows the definition of AC/PC coordinate system

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5	Localization	Assign a localizer frame for CT or MRI localization Perform automatic detection of localizer rods
6	Image Fusion	Align available image sets automatically, manually or using landmarks for various combinations of images sets and modalities such as CT, MRI, PET and SPECT. Visual verification of alignment.
7	Object Creation	Outline anatomical structures using manual or automatic segmentation methods. Advanced manipulation for 3D objects with scaling, logical operations and object splitting. Volumetric measurements based on the created 3D objects
8	Advanced Object Planning	Mirror and split segmented structures
9	BOLD MRI mapping	Processing of blood oxygen level dependent (BOLD) MRI data Definition of block design functional task, calculation of activation areas based on BOLD MRI data, time series view for activation signal, creation of 3D objects from activation areas
10	Fiber Tracking	Processing of diffusion tensor imaging (DTI) using various ways to define and combine seed regions of interest. Definition of multiple fiber bundles and creation of 3D objects from fiber bundles. Volumetric measurements and detailed fiber information
11	Trajectory planning	Plan pathways for surgical instruments or resection, definition of entry, target points and diameter for trajectories
12	Stereotactic planning	Planning of stereotactic trajectories Usage of AC/PC coordinates and Schaltenbrandt-Wahren atlas Calculation of stereotactic arc settings for planned trajectories
13	Electrode recording	Planning of parallel electrode tracks Enter and display microelectrode recording and stimulation results, display information stepwise along tracks
14	Save and Export	Save the current treatment plan to the patient folder Export the results to the navigation, as DICOM or STL format

The iPlan software can be used on a dedicated Brainlab system or other platforms with defined minimum requirements.

The iPlan software can be mainly used in combination with the Brainlab devices: iPlan Net, Digital Lightbox, VectorVision navigation, Kolibri navigation.

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Application performance testing
On different levels of development (module, subsystem, system) specific bench and integration tests were conducted. Internal standards were tested and documented as conformance report, environment compatibility and interfaces. Compatibility with previous version and comparable workflows to predicate devices were documented in corresponding review protocols.

Side-by-side comparison testing of the new version of iPlan with it's predicate device was conducted to determine substantial equivalences of the new version of iPlan with it's predicate version.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 3 2011

BrainLab AG
c/o Mr. Alexander Schwiersch
Regulatory Affairs Manager
Kapellenstrasse 12
Feldkirchen
Germany 85622

Re: K101627
Trade/Device Name: iPlan Cranial, iPlan Stereotaxy, iPlan ENT, iPlan Spine, iPlan View
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: May 13, 2011
Received: May 25, 2011

Dear Mr. Schwiersch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Indications for Use

510(k) Number (if known): K101627

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Prescription Use ___X___ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K101627

Prescription Use X
(Per 21 CFR 801.109)